Washington Law Review

Volume 65 | Number 3

7-1-1990

Regulating Physician Investment and Referral Behavior in the Competitive Health Care Marketplace of the '90s—An Argument for Decentralization

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REGULATING PHYSICIAN INVESTMENT AND REFERRAL BEHAVIOR IN THE COMPETITIVE HEALTH CARE MARKETPLACE OF THE '90s—AN ARGUMENT FOR DECENTRALIZATION

Abstract: Congress regulates the investment and referral practices of physicians through the federal Anti-Fraud and Abuse statute. The Anti-Fraud and Abuse statute, however, limits the ability of physicians to adapt their investment and referral practices to an increasingly competitive health care industry. In order to restrict fraudulent practices without restricting competition, the authority to regulate physician investment and referral practices should be returned to the states, who can recognize and exempt beneficial competitive practices from the reach of the applicable state statutes.

The last decade has witnessed a dramatic evolution in the delivery and payment of health care services in the United States. Competition has restructured the health care industry.[1] Individual practitioners face increased competition from new corporate forms of health care providers, whose structure enables them to better respond to market and regulatory changes.

Federal Medicare[2] and Medicaid[3] laws, however, have been slow to respond to the new era of competitive health care. Specifically, the law governing physician investment and referral practices—the Medicare-Medicaid Anti-Fraud and Abuse Amendment[4]—fails to conform to changes in the delivery of health care. The Anti-Fraud and Abuse statute regulates a wide variety of physician activity.[5] This Comment focuses on the application of the Anti-Fraud and Abuse statute to the investment and referral practices of physicians, as current restrictions on these practices pose a formidable barrier to delivering cost-effective health care.

Congress enacted the Anti-Fraud and Abuse statute to address the improper use of federal health care funds. The statute, however, actually promotes the inefficient use of federal funds by discouraging cost-efficient investment and referral arrangements between health care providers. Because the necessary balance between regulation and

1. *See generally* P. STARR, THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE (1982).
2. *See infra* note 16 and accompanying text (describing the Medicare program).
3. *See infra* note 18 and accompanying text (describing the state Medicaid programs).
4. 42 U.S.C.A. § 1320a-7b(b) (West Supp. 1989) [hereinafter Anti-Fraud and Abuse statute].
5. In addition to prohibiting certain physician investment and referral behavior, the Anti-Fraud and Abuse statute prohibits other fraudulent practices, such as false representation in applications for Medicare-Medicaid reimbursement. *See generally* MEDICARE FRAUD AND ABUSE, UNDERSTANDING THE LAW (J. Johnson & J. Seifert eds. 1986) [hereinafter UNDERSTANDING THE LAW].

competition in the health care industry differs among the states, the states should regulate the investment and referral practices of physicians.

I. PHYSICIANS WHO REFER PATIENTS FOR FINANCIAL GAIN

A. The Conflict of Interest

A physician who refers patients to health care providers in which the physician holds an investment risks a potential conflict of interest.[6] The physician's duty to the patient, traditionally considered primary to all other duties,[7] may be compromised by the possibility of financial gain from the referral. The referring physician may elevate monetary self-interest over the patient's medical interest in referring patients to a facility in which the physician has invested.

The Office of the Inspector General (OIG) of the United States Department of Health and Human Services (HHS) measured the prevalence of financial arrangements between physicians and referral facilities[8] in 1989.[9] The OIG estimated that 11.8 percent of physicians refer Medicare patients to a facility in which the physicians carry an ownership interest.[10] The OIG survey also targeted physicians who invest in independent clinical laboratories and discovered that these investing physicians authorize 45 percent more laboratory referrals than non-

6. Conflicts between a physician's financial investments and the physician's allegiance to a patient must be resolved to the patient's benefit. AMERICAN MEDICAL ASSOCIATION, CURRENT OPINIONS OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS OF THE AMA § 8.03 (1986).

Referrals by physicians without an investment or other financial interest in a referral facility may also trigger a conflict of interest. For example, physicians who refer patients to other health care providers in exchange for a referral or finder's fee, create a conflict between the physician's financial interest and the patient's medical interest. This Comment, however, does not address referrals by physicians who do not have an investment interest in referral facilities.

7. "The health of my patient will be my first consideration." 4 ENCYCLOPEDIA OF BIOETHICS 1749 (W. Reich ed. 1978) (excerpt from the Geneva Declaration, considered the modern version of the Hippocratic Oath).

8. Referral facilities provide a broad range of health care services not generally offered by physicians. For example, physicians refer patients to laboratories, pharmacies, and durable medical equipment suppliers. In addition, physicians refer patients to specialized health care providers, such as radiologists.

9. OFFICE OF THE INSPECTOR GEN., DEP'T OF HEALTH AND HUMAN SERVS., FINANCIAL ARRANGEMENTS BETWEEN PHYSICIANS AND HEALTH CARE BUSINESSES, REPORT TO CONGRESS (Doc. No. OAI-12-88-01410) (May 1989) [hereinafter OIG REPORT].

10. *Id.* at app. B, table B1. According to the OIG report, "referring physicians invest in a wide range of businesses, including . . . laboratories; durable medical equipment suppliers; home health agencies; hospitals; nursing homes; ambulatory surgical centers; and health maintenance organizations." *Id.* at iii.

investing physicians.[11] The OIG estimated that this increased use of laboratory services cost the Medicare program an additional $28.1 million in 1987.[12] Although the accuracy of these statistics may be challenged,[13] they demonstrate a need to ensure that patient needs—rather than profit motives—direct the referral decisions of physicians.[14]

B. The Federal Government's Interest in Regulating Physician Investment and Referral Behavior

Congress regulates the investment and referral practices of physicians who treat persons enrolled in the Medicare and Medicaid programs because such practices may add to the cost of medical treatment.[15] The Anti-Fraud and Abuse statute protects the Medicare and Medicaid programs from unnecessary costs charged by physicians who order additional referrals to maximize the return on their investment.

1. The Medicare-Medicaid Reimbursement System

Medicare provides federal monies for medical services received by eligible elderly, disabled, and persons with end-stage renal failure.[16] Physicians receive payment for treating Medicare beneficiaries by submitting an application for Medicare reimbursement to a federally-

11. *Id.*

12. The increased use estimate is subject to a 90 percent confidence interval, with a lower limit of $13.7 million and an upper limit of $42.4 million. *Id.* at app. B. In 1987, $28.1 million represented .03 percent of federal Medicare expenditures, which approximated $79.6 billion in that year. CALIFORNIA ASS'N OF HOSPITALS AND HEALTH SYS., 1989 HOSPITAL FACT BOOK 18, table 1.12 (1989).

13. The American Medical Association (AMA) challenged the OIG estimate; the AMA's own survey revealed a lower percentage, 7.1 percent, of physicians referring patients to a facility in which they have an investment interest. *Statement of AMA to the Subcomm. on Health and the Env't, Comm. on Energy and Commerce* app. 1 (June 8, 1989) (statement of J. Todd, MD) (copy on file with *Washington Law Review*) [hereinafter *AMA Statement*].

14. The OIG report did not inquire whether the additional referrals represented medically necessary procedures or whether financial concerns motivated the additional referrals. A case-by-case investigation of the reasons for the additional referrals would have revealed whether medical necessity or financial gain motivated the additional referrals, and would have further isolated the magnitude of the conflict of interest problem posed by physician investment in referral facilities.

15. A physician who sends Medicare or Medicaid patients to a referral facility in which the physician has an investment interest has a financial incentive to abuse the referral privilege and authorize unnecessary referrals, which may increase the cost of health care.

16. 42 U.S.C.A. § 1395c (West Supp. 1989). Medicare Part A provides reimbursement for services performed by hospitals and other institutional providers. *Id.* Medicare Part B provides reimbursement for services performed by physicians and other health care professionals in a non-institutional setting. *Id.* § 1395j.

approved insurance carrier.[17] In contrast, physicians receive payment for treating Medicaid beneficiaries by submitting reimbursement applications directly to a state agency.[18] Medicaid is a cooperative federal-state program that provides payments for medical services for the poor, the disabled, the elderly, and other qualified recipients.[19] The federal government partially subsidizes Medicaid programs by issuing matching grants to the states.[20] The states control expenditures of federal Medicaid grants and retain the authority to formulate eligibility requirements for Medicaid recipients.[21]

Medicare and Medicaid programs currently reimburse physicians according to a retrospective system of payment; physicians calculate the reimbursement rate after delivering the necessary medical services to Medicare or Medicaid patients. The actual cost of the services received determines the amount of reimbursement.[22]

2. *The Federal Anti-Fraud and Abuse Statute*

The Medicare-Medicaid Anti-Fraud and Abuse statute[23] regulates the investment and referral practices of physicians. Congress enacted

17. *Assignment,* 1 Medicare & Medicaid Guide (CCH) ¶ 3350 (Aug. 1989). The insurance carrier pays the physician 80 percent of the reasonable charge over and above the deductible. The physician collects the remaining 20 percent and any applicable deductible directly from the Medicare patient. *Id.*

18. Although state Medicaid programs vary, most states reimburse Medicaid providers through a state agency. The Arizona program illustrates a different approach. Arizona allocates its Medicaid dollars through health maintenance organizations. *See* Babbitt & Rose, *Building a Better Mousetrap: Health Care Reform and the Arizona Program,* 3 YALE J. ON REG. 243, 263 (1986).

19. 42 U.S.C.A. § 1396 (West 1983 and Supp. 1989).

20. *Id.* § 1396b.

21. *Id.* § 1396a.

22. The reasonableness of the costs claimed by physicians constitutes the primary limitation on Medicare retrospective reimbursement. *Id.* § 1395x(v) (defining reasonable cost).

Nationally, Medicare considers 84 percent of a physician's average fee to non-Medicare patients a reasonable fee for Medicare patients. Therefore, Medicare reimburses physicians 67.2 percent (or 80 percent of 84 percent) of their average fees. On average, state Medicaid programs reimburse physicians for only 65 percent of physicians' average fees. T. GRANNEMANN & M. PAULY, CONTROLLING MEDICAID COSTS, FEDERALISM, COMPETITION & CHOICE 69 (1983).

23. 42 U.S.C.A. § 1320a-7b(b) (West Supp. 1989):

> (1) [W]hoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—(A) in return for referring an individual to a person for the furnishing of any item or service for which payment may be made . . . under [Medicare] . . . or a State health care program . . . shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.
>
> (2) [W]hoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—(A) to refer an individual to a person for the furnishing

the statute to deter physicians from advancing their financial interest over the interests of Medicare and Medicaid patients.[24] The Anti-Fraud and Abuse statute imposes criminal sanctions on physicians who receive remuneration in exchange for referring Medicare or Medicaid patients to other health care providers.[25] In addition, the statute imposes criminal sanctions on referral facilities that solicit or induce referrals by remunerating the referring physicians.[26]

United States v. Greber[27] illustrates the prevailing judicial interpretation of the Anti-Fraud and Abuse statute. In *Greber*, the Third Circuit Court of Appeals imposed criminal sanctions on a referral facility that remunerated referring physicians.[28] The court emphasized that criminal liability results with mere proof that the physician's financial interest may induce the physician to authorize unnecessary referrals.[29] Whether the physician's financial interest actually induced the referral is immaterial.[30]

The Anti-Fraud and Abuse statute employs the term remuneration to encompass a broad range of activities.[31] Even indirect payments between physicians and referral facilities, such as investment dividends, constitute remuneration.[32] As a result, physicians who invest in and refer patients to the same referral facility risk prosecution under the criminal Anti-Fraud and Abuse statute.

. . . of any item or service for which payment may be made . . . under [Medicare] . . . or a State health care program . . . shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

24. H.R. REP. NO. 393, 95th Cong., 1st Sess. 44, *reprinted in* 1977 U.S. CODE CONG. & ADMIN. NEWS 3047.

25. 42 U.S.C.A. § 1320a-7b(b)(1). The Civil Monetary Penalties Laws of 1981 and 1987 also deter physicians from profiting from referrals by providing the government with a civil remedy. The laws permit courts to impose fines up to $2,000 for each violation on physicians who file false or fraudulent Medicare or Medicaid claims. *Id.* § 1320a-7a(a).

The Medicare and Medicaid Patient and Program Protection Act of 1987 (MMPPPA) added another weapon to the federal anti-fraud and abuse arsenal. Upon conviction of fraudulent behavior by a state or federal authority, the MMPPPA provides for the exclusion or suspension of convicted physicians from the Medicare and Medicaid programs. Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93, § 2, 101 Stat. 680 (codified as amended at 42 U.S.C.A. § 1320a-7 (West Supp. 1989)).

26. 42 U.S.C.A. § 1320a-7b(b)(2).

27. 760 F.2d 68 (3d Cir.), *cert. denied,* 474 U.S. 988 (1985) (payment of "interpretation fees" by a referral facility to referring physicians violates the criminal Anti-Fraud and Abuse statute).

28. *Id.* at 70–72.

29. *Id.* at 72.

30. *Id.* at 71.

31. 42 U.S.C.A § 1320a-7b(b)(1) (West Supp. 1989).

32. The HHS has commented that "[a]s written, the [statute] . . . is so broad that it could be interpreted literally . . . to prohibit a physician from receiving dividend payments." 54 Fed. Reg. 3090 (supplementary information to proposed rule to be codified at 42 C.F.R. pt. 1001) (proposed Jan. 23, 1989).

The Anti-Fraud and Abuse statute may permit a physician to invest in and send Medicare and Medicaid patients to the same referral facility in two limited circumstances.[33] First, a physician may send patients to a referral facility that has a bona fide employment relationship with the referring physician.[34] Physicians who invest in referral facilities may argue that their investment interest conveys employer status to the investing physicians, thus triggering the exception. The exception, however, has not been applied to permit physicians to invest in and refer patients to the same health care provider.[35]

Second, the HHS proposes that physicians may avoid the reach of the Anti-Fraud and Abuse statute by limiting their investments to referral facilities with over $5,000,000 in assets and over 500 shareholders.[36] This proposed exception, however, excludes only a limited number of investments from criminal punishment because not all referral facilities satisfy the minimum asset and shareholder conditions of the exception.

33. The Anti-Fraud and Abuse statute contains four exceptions. The second and fourth exceptions address investment agreements between physicians and referral facilities. 42 U.S.C.A. §§ 1320a-7b(b)(3)(B), (D). The first and third exceptions address compensation agreements between physicians and referral facilities that do not involve physician investment in referral facilities, such as volume discount arrangements. *Id.* §§ 1320a-7b(b)(3)(A), (C). Compensation agreements not involving physician investment are beyond the scope of this Comment.

34. *Id.* § 1320a-7b(b)(3)(B). The Anti-Fraud and Abuse statute does not define bona fide employment relationship. HHS recommends that the Anti-Fraud and Abuse statute incorporate the common law definition of employee codified in the tax code at 26 U.S.C.A. § 3121(d)(2) (West 1989). 54 Fed. Reg. 3095 (to be codified at 42 C.F.R. pt. 1001.952(i)) (proposed Jan. 23, 1989).

35. If courts permit physicians to use the employer exception to circumvent the investment prohibitions of the Anti-Fraud and Abuse statute, greater consolidation among health care providers may result, thus decreasing competition in health care delivery. Economist Mark V. Pauly warns of the anti-competitive implications of such conduct in *The Ethics and Economics of Kickbacks and Fee Splitting,* 10 THE BELL J. ECON. 349 (1979).

36. Investment in most publicly traded drug companies, for example, would fall under this proposed exception. Thus, a physician can prescribe a drug manufactured by a publicly traded company in which the physician owns stock without risking criminal sanction. 54 Fed. Reg. 3094 (to be codified at 42 C.F.R. pt. 1001.952(a)) (proposed Jan. 23, 1989). HHS proposed this rule in 1989, pursuant to the authority delegated by Congress to promulgate additional exceptions to the Anti-Fraud and Abuse statute. 42 U.S.C.A. § 1320a-7b(b)(3)(D). This Comment assumes the final rule will mirror the language in the proposed rule.

Interestingly, HHS originally proposed a broad category of permissible physician investments on December 23, 1988. 53 Fed. Reg. 51,856. Five days later, however, the HHS withdrew this proposal. 53 Fed. Reg. 52,448 (1988).

3. *The Prospective Payment System*

In the 1980s, Congress recognized that the retrospective payment system[37] does not encourage cost-effective patient care.[38] Retrospective payment discourages physicians from considering the cost-effectiveness of alternative treatments because actual treatment costs determine the physician's reimbursement. Thus, Congress implemented the prospective payment system (PPS)[39] as a financial incentive for health care providers to reduce Medicare and Medicaid costs by delivering cost-effective treatment.[40] Prospective payment motivates physicians to deliver cost-effective care by setting a predetermined ceiling for reimbursement.

Congress first enacted PPS in 1982 to reduce Medicare and Medicaid payments to hospitals.[41] The success of the hospital program encouraged Congress to expand PPS to physicians.[42] Beginning in 1992, physicians treating Medicare or Medicaid eligible patients will receive prospective reimbursement.[43] Physicians will know their reimbursement allowances prior to treating Medicare-Medicaid patients, because a predetermined schedule of uniform physician fees will predict the amount of reimbursement.[44]

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37. *See supra* note 22 and accompanying text (explaining the retrospective payment system).

38. *Introduction,* 1 Medicare & Medicaid Guide (CCH) ¶ 4203 (Sept. 1986).

39. Congress authorized the creation of a prospective payment system for hospital services covered by Medicare in 1982. Tax Equity and Fiscal Responsibility Act of 1982, Pub. L. No. 97-248, § 101, 96 Stat. 324 (1982) (current version at 42 U.S.C.A. § 1395ww (West Supp. 1989)). Congress extended the prospective payment system to physician services covered by Medicare in 1989. Omnibus Budget Reconciliation Act of 1989, Pub. L. No. 101-239, § 6102, 103 Stat. 2169 (1989) (to be codified at 42 U.S.C. 1395w-4).

40. *Diagnosis-Related Group (DRG) Classifications,* 1 Medicare & Medicaid Guide (CCH) ¶ 4203 (Sept. 1986).

41. Hospitals received PPS reimbursement beginning in 1983, with the establishment of diagnosis-related groups (DRG). Under the DRG system, the patient's diagnosis—not the hospital bill—determines the amount of Medicare-Medicaid reimbursement. As of March 1990, the Health Care Financing Administration (HCFA) has categorized 477 DRGs through which hospitals receive essentially the same fee for treating patients with similar diagnosis. Changes to the Inpatient Hospital Prospective Payment System and Fiscal Year 1990 Rates, 54 Fed. Reg. 36,452, 36,454 (1989) (codified at 42 C.F.R. pt. 412).

42. 135 CONG. REC. S14,423 (daily ed. Oct. 31, 1989).

43. Omnibus Budget Reconciliation Act of 1989, Pub. L. No. 101-239, § 6102, 103 Stat. 2169 (1989) (to be codified at 42 U.S.C. 1395w-4). Congress based the new physician payment plan on the Resource-Based Relative Value Scale developed by W.C. Hsiao. *See generally* Hsiao, Braun, Dunn, Becker, *Resource-Based Relative Values: An Overview,* 260 J.A.M.A. 2347 (1988).

44. Physician fees will not be entirely uniform. Congress permits the HCFA to make adjustments for geographic discrepancies in practice costs. Omnibus Budget Reconciliation Act of 1989, Pub. L. No. 101-239, §§ 6102(a), 1848(c), 103 Stat. 2171 (1989) (to be codified at 42 U.S.C. § 1395w-4).

Beginning January 1, 1992, the transition from the retrospective to prospective payment will occur in five annual phases implemented by the HCFA. *Id.* §§ 6102(a), 1848(a)(2), 103 Stat. at

C. *The States' Interest in Regulating Physician Investment and Referral Behavior*

Many states have formed agencies to enforce the Anti-Fraud and Abuse statutory restrictions on physician investment behavior. In addition, many states have enacted their own restrictions on physician investment and referral practices. The state regulatory schemes, however, differ from one another because investment needs differ among the states.

1. *State Enforcement of Federal Regulations*

States receiving federal Medicaid grants must investigate fraud and report their findings to the Health Care Financing Administration (HCFA).[45] States failing to meet the inspection and reporting requirements risk a reduction or loss of federal Medicaid grants.[46] In thirty-nine states, federally-subsidized Medicaid Fraud Control Units (MFCUs) satisfy the inspection and reporting requirements.[47] Congress established a framework for the states to form MFCUs and to delegate broad investigative and prosecutorial authority to MFCUs.[48] In states still lacking MFCUs, the Office of the State Attorney General typically assumes the responsibility for investigating and prosecuting Medicare and Medicaid fraud.[49]

2. *State Regulation of Physician Investment and Referral Behavior*

State statutes also restrict the investment and referral behavior of physicians. The states have traditionally controlled the investment behavior of their citizens.[50] Through their laws governing investment

2169. Congress "hoped that this transition would reduce incentives for behavioral responses to price changes by physicians." 135 CONG. REC. S13,218 (daily ed. Oct. 12, 1989).

45. 42 C.F.R. pt. 455.15 (1988) (investigation requirements). *Id.* pt. 455.17 (reporting requirements). The HCFA, a division of HHS, administers the Medicare and Medicaid programs.

46. 42 U.S.C.A. § 1396(p) (West. Supp. 1989).

47. Thirty-eight states managed MFCUs in 1989. OFFICE OF INSPECTOR GENERAL, DEP'T OF HEALTH AND HUMAN SERVS., SEMIANNUAL REPORT 22 (Oct. 1, 1988-Mar. 31, 1989) (hereinafter SEMIANNUAL REPORT). Alaska will add the thirty-ninth MFCU in 1990. Telephone interview with Richard Stern, Attorney, Inspector Gen. Div., Office of Gen. Counsel, U.S. Dep't of Health & Human Servs. (Feb. 28, 1990).

48. 42 U.S.C.A. §§ 1396b(a), (q) (West Supp. 1989). *See also* 42 C.F.R. pt. 455.21 (1988) (HCFA minimum guidelines for state MFCUs).

49. Telephone interview with Richard Stern, Attorney, Inspector Gen. Div., Office of Gen. Counsel, U.S. Dep't of Health & Human Servs. (Feb. 28, 1990).

50. "Given the long history of state common-law and statutory remedies against . . . unfair business practices, it is plain that this is an area traditionally regulated by the States." California v. ARC America Corp., 109 S. Ct. 1665 (1989) (footnotes omitted) (federal law does not preempt state indirect purchaser laws).

in corporations, partnerships, sole proprietorships, and their many variations, the states control physician investment in these enterprises.[51] Moreover, the states govern the referral behavior of physicians through statutory prohibitions on unprofessional physician conduct. Such statutes, enforced by disciplinary proceedings, punish improper or fraudulent referral practices.[52]

States also regulate and punish physicians' fraudulent investment and referral behavior through their own anti-fraud and abuse statutes.[53] These state statutes may further restrict fraudulent investment and referral practices of physicians who participate in Medicaid or other state health programs.[54]

3. *Varying Health Care Delivery Among the States*

Health care needs vary among the states. For instance, Washingtonians rarely confront the need Alaskans face for additional kidney dialysis centers.[55] Demographic variations, income disparity, cultural differences, and other factors contribute to the inability of sparsely populated states, such as Alaska, to attract a sufficient number of dialysis centers.[56]

The states of Utah and Nevada provide another example of varying state health care needs. The different alcohol consumption rates of the citizens of Utah and Nevada contribute to their dramatically different rates of liver cirrhosis.[57] Many Utah residents are Mormons, and therefore abstain from consuming alcohol.[58] By contrast, many Nevada residents consume alcohol.[59] Because alcohol consumption

51. *See, e.g.*, WASH. REV. CODE titles 23–25 (1989).

52. For example, the State of Washington considers the promotion for personal gain of any unnecessary or inefficacious drug, device, treatment, procedure, or service as unprofessional conduct. WASH. REV. CODE § 18.130.180(16) (1989). For a comprehensive list of state statutes regulating physician conduct, see U.S. DEP'T OF HEALTH, EDUC., AND WELFARE, STATE REGULATION OF HEALTH MANPOWER app. A (1977) (DHEW Pub. No. (HRA) 77-49).

53. *See, e.g.*, WASH. REV. CODE §§ 19.68.010, 51.48.280 (1989).

54. For a compilation of 37 state statutes that address fraudulent physician conduct, see UNDERSTANDING THE LAW, *supra* note 5, at 36–39. For a discussion of the countless state and federal regulatory burdens imposed on physicians, see Ellman, *Monitor Mania: Physician Regulation Runs Amok!*, 20 LOY. U. CHI. L.J. 721 (1989).

55. For a statistical comparison of state dialysis rates, see Relman & Rennie, *Treatment of End-Stage Renal Disease: Free but Not Equal*, 303 NEW ENG. J. MED. 996 (1980).

56. *Id.* at 998.

57. V. FUCHS, WHO SHALL LIVE? HEALTH, ECONOMICS, AND SOCIAL CHOICE 53–54 (1974).

58. *Id.* at 53. Utah's per capita beer consumption, for example, ranks lowest in the nation. BUREAU OF THE CENSUS, U.S. DEP'T OF COMMERCE, STATISTICAL ABSTRACT OF THE UNITED STATES 107 (107th ed. 1986).

59. Nevada's per capita beer consumption ranks second highest in the nation. *Id.*

contributes to liver disease, Nevada residents require the services of liver specialists more frequently than their Utah counterparts.[60]

As a result of each state's distinct health care needs, a variety of health care delivery systems emerge. Depending on the needs and resources of the community, physicians practicing alone, in a partnership, or in a corporate setting may deliver health care. The growth of health care corporations signifies an important transformation in the delivery of and payment for health care. From 1980 to 1987, the number of health maintenance organizations (HMOs)[61] jumped from 235 to 647.[62] Another type of physician corporation, the preferred provider organization (PPO),[63] also grew in the last decade. PPO enrollment increased from 1.3 million Americans in December 1984 to 16.5 million in July 1986.[64] Commentators predict that most patients in the 1990s will be treated by physician-members of health care corporations.[65] Physicians who practice in HMOs, PPOs, and other corporate providerships will attract an increasing number of patients away from sole or group practitioners because of their reduced treatment costs,[66] convenient on-site ancillary services,[67] and effective marketing techniques.[68]

Yet health care corporations have not uniformly developed among the states.[69] The number of HMOs in rural and urban areas, for

60. In Nevada, 18.1 per 100,000 residents died of chronic liver disease in 1986. In Utah, the rate was dramatically lower, only 7.3 deaths per 100,000 in 1986. CENTERS FOR DISEASE CONTROL, *Chronic Disease Reports: Deaths from Chronic Liver Disease—United States, 1986,* 38 MORBIDITY AND MORTALITY WEEKLY REP. 798 (1989).

61. Physicians practicing in an HMO deliver health care to members of an enrolled group in exchange for a fixed periodic payment. R. SHOULDICE & K. SHOULDICE, MEDICAL GROUP PRACTICE AND HEALTH MAINTENANCE ORGANIZATIONS 10 (1978). Individual Practice Associations (IPAs) represent a contractual variation of HMOs. While HMO physicians usually deliver health care only to HMO-enrolled patients, IPA physicians typically maintain their individual practices as well as treat IPA-enrolled patients. *Id.* at 105.

62. NAT'L CENTER FOR HEALTH STATISTICS, HEALTH UNITED STATES 1988 173 (Mar. 1989) (DHHS Pub. No. (PHS) 89-1232).

63. Preferred provider organizations are contractual arrangements between health care consumers and health care providers, typically hospitals and physicians, in which the providers agree to supply health care at a discounted rate. Koch, *Financing Health Services,* in INTRODUCTION TO HEALTH SERVICES 335, 365 (S. Williams & P. Torrens eds. 1988).

64. Gabel, Jajich-Toth, Williams, Loughran, & Haugh, *The Commercial Health Insurance Industry in Transition,* 6 HEALTH AFFAIRS 46, 52 (1987).

65. P. STARR, *supra* note 1, at 440.

66. Williams, *Ambulatory Health Care Services,* in INTRODUCTION TO HEALTH SERVICES 124, 144 (S. Williams & P. Torrens eds. 1988).

67. On-site ancillary services refer to health care services performed by non-physicians, such as performing x-rays, analyzing laboratory tests, and dispensing prescription medication.

68. R. SHOULDICE & K. SHOULDICE, *supra* note 61, at 199–242.

69. Emmons, *Changing Dimensions of Medical Practice Arrangements,* 45 MED. CARE REV. 101, 115 (1988).

example, differ significantly. In 1986, only 22 percent of rural physicians participated in HMOs, while 47 percent of urban physicians participated in HMOs.[70] In rural and small town settings, physicians practicing alone or in small groups continue to meet the health care needs of their communities.[71]

II. A CALL FOR DECENTRALIZATION

Competition among health care providers has intensified in recent years, encouraged in part by the federal government. When physicians attempt to respond to competitive pressures by forming cost-effective practices, however, the investment restrictions of the federal Anti-Fraud and Abuse statute present a significant impediment. Increased competition calls for a new approach to regulating physician investment and referral behavior—decentralization. Congress should decentralize the regulation of physician investment practices by allowing the states to regulate potentially fraudulent physician investment and referral practices.

A. The Conflict Between Competition and the Anti-Fraud and Abuse Statute

Two forces have played an important role in activating competition among health care providers—the rise of physician corporations and the advent of the prospective payment system. First, individual practitioners face greater competition from new corporate forms of health care providers, whose structure enables them to better respond to market and regulatory changes.[72] Increasingly, physicians may consider grouping their talents in some type of corporate arrangement. The Anti-Fraud and Abuse statute, however, limits the extent that physicians in such an arrangement can participate in the Medicare and Medicaid programs.

The federal Anti-Fraud and Abuse statute prohibits physician corporations from using certain monetary incentives to encourage member physicians to deliver cost-effective medical care.[73] For instance,

70. *Id.* at 115.

71. *See, e.g.*, PHYSICIAN MARKETPLACE STATISTICS 1989 85, table 52 (M. Gonzalez ed. 1989) (statistics showing geographical distribution of self-employed physicians by size of practice).

72. *See supra* notes 61–68 and accompanying text (discussing the growth of corporate health care providers).

73. Although corporate providers, such as HMOs, existed when Congress enacted the Anti-Fraud and Abuse statute, neither the statute nor its legislative history mentions the investment and referral behavior of physicians who practice in a corporate setting. H.R. REP. NO. 393, 95th Cong., 1st Sess. 1, *reprinted in* 1977 U.S. CODE CONG. & ADMIN. NEWS 3039.

many HMOs award monetary bonuses to physicians who provide cost-effective medical care, such as admitting fewer patients to hospitals.[74] A literal reading of the Anti-Fraud and Abuse statute suggests that the statute prohibits bonus payments if the HMO seeks to treat Medicare or Medicaid patients.[75] But HMO bonus payments do not encourage or result in actual fraud or abuse of Medicare-Medicaid funds. Rather, the bonus payment rewards the HMO physician for conserving federal funds. By broadly defining the term remuneration to include cost-effective remunerations, such as HMO bonus payments, the federal Anti-Fraud and Abuse statute penalizes the attempts of corporate health care providers to reduce health care costs.

Prospective payment is the second competitive force in health care. The federal government amplified the competitive pressures affecting physicians by extending the prospective payment system to physician Medicare-Medicaid reimbursement. Under the uniform reimbursement system mandated by PPS, the federal government will reimburse physicians at a uniform rate, regardless of actual treatment costs.[76] If treatment costs consistently exceed reimbursement rates, physicians may be compelled to either refuse to treat Medicare and Medicaid patients or develop more cost-effective practices.[77] The Anti-Fraud and Abuse statute, however, erects a formidable barrier to many cost-effective practices. The statute limits a physician's ability to respond to competitive pressures by prohibiting a physician from referring patients to facilities in which the physician has an investment interest.[78]

Home dialysis exemplifies the barriers to cost-effective responses to increased competition. Home-administered kidney dialysis costs less

74. R. SHOULDICE & K. SHOULDICE, *supra* note 61, at 16.

75. The bonus payment in this illustration may subject the HMO and the physician to criminal sanctions because the bonus can be interpreted as illegal "remuneration" in exchange for referring a patient for non-hospital treatment. *See* 42 U.S.C.A. § 1320a-7b(b) (West Supp. 1989).

76. *See supra* notes 39–44 and accompanying text (examining the prospective payment system as applied to physicians' services).

77. Prospective reimbursement presents special problems for some physicians. The cost of treating some patients will exceed the predetermined reimbursement rate; for other patients, it will fall below. This variance will create special problems for physicians whose treatment costs continually surpass the reimbursement rate. The current retrospective payment system reimburses physicians on average only 67.7 percent of the full cost of their Medicare services. GRANNEMANN & PAULY, *supra* note 22, at 69. Prospective reimbursement is less likely to approach costs because prospective reimbursement is calculated independently from actual costs. *See supra* notes 43–44 (examining the prospective payment system as applied to physicians' services).

78. *See supra* note 32.

than hospital-administered dialysis.[79] Home dialysis also provides other important advantages to some patients, such as convenience and comfort. The investment restrictions in the Anti-Fraud and Abuse statute, however, prevent physicians from using their capital resources to offer the advantages of home dialysis to their patients.[80] In small communities, which provide an insufficient market to attract large corporate investors, local physicians may decide to pool their funds to provide needed home dialysis services. The statute, however, would prevent physicians from referring their Medicare or Medicaid patients to their home dialysis service. Liberated from the Anti-Fraud and Abuse restrictions, physicians could apply their financial resources to provide their patients with proper and cost-effective care, such as home dialysis.[81]

B. Judicial Interpretations and Federal Statutory Amendments Provide No Effective Alternatives

Both the federal courts and Congress have failed to interpret or amend the Anti-Fraud and Abuse statute to exclude cost-effective medical treatment from the reach of the statute's criminal sanctions. By refusing to consider facts justifying the remuneration, the court in *United States v. Greber*[82] hindered physicians' efforts to initiate the delivery of cost-effective medical care.[83] In some cases, a physician may respond to competitive pressures by investing in and referring patients to a cost-effective medical provider.[84] *Greber,* however, directs courts to ignore cost-effectiveness defenses.[85] Courts need only establish that the remuneration may possibly induce unnecessary referrals.[86]

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79. Recognizing that home kidney dialysis costs less to administer than hospital dialysis, the HCFA reimburses home dialysis providers at a lower rate than hospital dialysis providers. In 1986, the HCFA set the composite rate of home dialysis reimbursement at $96.18 per treatment. The hospital composite rate equalled $118.65 per dialysis treatment. Notice, 51 Fed. Reg. 29,411 (Aug. 15, 1986). Considering that most chronic dialysis patients receive dialysis three times per week, home dialysis saves the Medicare program approximately $3,500 per patient per year.

80. *See supra* note 32.

81. In large communities, where more than one home dialysis provider may be available, the Anti-Fraud and Abuse statute may not conserve federal Medicare funds by permitting referring physicians to establish a home dialysis service. Nevertheless, the statute may undermine the patient-physician relationship by forcing physicians to refer patients to a provider that the physician thinks provides substandard medical care.

82. 760 F.2d 68 (3rd Cir.), *cert. denied,* 474 U.S. 988 (1985).

83. *Id.* at 71.

84. *See supra* notes 79–81 and accompanying text (discussing physician investment in a home dialysis service).

85. *Greber,* 760 F.2d at 71.

86. *Id.*

The federal courts are reluctant to revise the *Greber* doctrine to reflect Congressional pressures from PPS for cost-effective health care delivery. In *United States v. Bay State Ambulance and Hospital Rental Services,*[87] the First Circuit strictly adhered to the *Greber* interpretation of the Anti-Fraud and Abuse statute.[88] The *Bay State* opinion did not address PPS or other recent transformations in the delivery and payment of medical care. In fact, the *Bay State* court voiced its reluctance to consult recent congressional action in interpreting an earlier enactment.[89]

Congressional efforts to remodel the statute have also fallen short. In 1987, Congress gave HHS the authority to add competitive investment and referral arrangements to the list of permissible arrangements.[90] Administrative delays resulting from rulemaking procedures, however, prevent the agency from promptly responding to competitive developments in the health care industry. When the health care market within a state reveals the cost-effectiveness of a given investment and referral practice, providers first must convince the HHS of its value. Then the HHS must propose a regulation and meet notice and comment requirements.[91] This may take years to accomplish.[92] Meanwhile, new competitive practices may emerge and require repetition of the approval procedure. HHS responses will constantly lag behind health care market changes, thus defeating the cost-saving goals of such programs as PPS.

The HHS recently exercised its authority to add exceptions to the Anti-Fraud and Abuse statute. The agency proposes to authorize physician investment in, and referral to, large publicly-traded corporations with a minimum of both $5,000,000 in assets and 500 shareholders.[93] This proposal illustrates that HHS intends to use its delegated authority to draft very specific, instead of general, excep-

87. 874 F.2d 20 (1st Cir. 1989) (ambulance company convicted for remunerating a hospital employee in exchange for referring medical emergencies).

88. *Id.* at 29–30. The Ninth Circuit also strictly observed the *Greber* doctrine in *United States v. Kats,* 871 F.2d 105, 108 (9th Cir. 1989) (partial owner of a medical clinic convicted for collecting a fee in exchange for referring blood and urine samples to a laboratory).

89. "[E]ven assuming that the statutory changes and proposed administrative actions show that . . . Congress never intended to criminalize the kind of payments involved here, courts are chary of allowing a subsequent Congress' comments on the intent of prior legislation to control." *Bay State,* 874 F.2d at 31.

90. 42 U.S.C.A. § 1320a-7b(b)(3)(D) (West Supp. 1989).

91. 5 U.S.C.A. § 553 (West 1977) (mandatory rulemaking procedures for administrative agencies).

92. As of April 1990, HHS still has not fulfilled Congress' 1987 request to promulgate additional exceptions to the Anti-Fraud and Abuse statute. 42 U.S.C.A. § 1320a-7b(b)(3)(D).

93. 54 Fed. Reg. 3094 (to be codified in 42 C.F.R. pt. 1001.952(a)) (proposed Jan. 23, 1989).

tions to the Anti-Fraud and Abuse statute.[94] These specific criteria provide little flexibility and fail to accommodate differences in investment and health care needs between the states. In some states, for example, physician investment in referral facilities with fewer than 500 shareholders may prove beneficial. By issuing specific criteria, the HHS discourages physicians and states from experimenting with cost-effective investment and referral practices in their communities. Decentralizing the authority to regulate physician investment in referral facilities would allow states to restrict the most fraudulent practices while allowing types of physician investment that will most benefit a particular state.

C. The Argument for State Regulation

Congress should return the authority to regulate the investment and referral behavior of physicians to the states. The states can apply their familiarity with the local health care industry to enact regulations that limit fraudulent practices and address local health care needs, without unduly hindering physicians' attempts to provide cost-effective medical care.

1. State Regulation Responds to Local Health Care Needs

The Anti-Fraud and Abuse statute fails to respond to important state differences in the delivery of health care. The federal statute places severe restrictions on the investment practices of physicians, providing only a few specific exceptions that do not contemplate community health care needs.[95] The statute impairs the efforts of health care providers to develop cost-effective and innovative responses to deficiencies in local health care delivery.[96]

Congress should devolve to the states the ability to regulate the referral practices of investing physicians.[97] State legislatures could then enact statutes that punish the most fraudulent practices, while

94. The explanatory comments to the proposed regulations confirm this assessment. The HHS stated that the department is currently considering "crafting an additional exemption to the . . . statute for certain limited partnerships and managing partnership interests that operate according to standards that we would prescribe." 54 Fed. Reg. 3090 (Jan. 23. 1989).

95. *See supra* notes 33–37 and accompanying text (describing two exceptions to the Anti-Fraud and Abuse statute).

96. *See supra* notes 79–81 and accompanying text (discussing physician investment in a home dialysis service).

97. Decentralizing the regulation of physician investment and referral behavior does not mandate decentralizing the regulation of all potentially fraudulent behavior. Regulating investment and referral behavior, however, requires a separate state approach because this behavior has an especially important effect on the local delivery of health care.

allowing beneficial physician investment practices. Congress could continue to maintain some control by requiring state statutes to meet some minimum federal threshold.[98]

All investment arrangements between physicians and referral facilities have the potential to encourage unnecessary referrals based solely on the physician's monetary interests.[99] Some investments, however, present a greater incentive for fraudulent conduct than others. For example, an investment that ties the rate of return directly to the volume of referrals provides a strong financial incentive for physicians to abuse their referral privilege.[100] In contrast, an investment offering a fixed rate of return, regardless of the number of patients referred to the facility, provides a less direct and less powerful incentive for unnecessary referrals.[101] States may discourage the former type of arrangement without broadly prohibiting physician investment in referral facilities.

An individual state is best suited to decide whether its particular health care needs warrant a more flexible approach to physician investment than the federal Anti-Fraud and Abuse statute currently provides. For example, in a rural community where important dialysis services are in short supply,[102] the state could relax physician investment rules to encourage local physicians to jointly invest in dialysis equipment.

Individual state regulation of physician investment and referral behavior will not result in more confusion.[103] Most physicians confine

98. Minimum guidelines, for example, might require the states to establish a statutory scheme and periodically report their progress to a federal regulatory agency, such as HHS. The federal agency, in turn, might conduct its own periodic review of the effectiveness of state programs. Aid to Families with Dependant Children typifies a state program in which Congress established minimum guidelines for the states to supplement. *See* 42 U.S.C.A. § 602 (West Supp. 1989).

99. *See supra* note 6 and accompanying text (discussing conflict of interest).

100. When a physician's return on investment is directly correlated with the number of patients referred by the physician, a seemingly innocuous investment may camouflage an illegal kickback. Kickbacks merit broad governmental prohibition because they provide strong financial inducement for referral fraud.

101. A physician who refers patients to a facility in which the physician has invested still receives a form of remuneration, albeit indirectly. The more referrals the facility receives, the greater the facility's total profits. Thus, the physician's return on investment increases with additional referrals. An investing physician's incentive to make unnecessary referrals, however, is diluted because the volume of referrals represents just one of many factors that contribute to the amount of return on the physician's investment.

102. A statistical comparison of state dialysis rates indicates "an extraordinary variation" in the use and availability of dialysis among the states. The statistics demonstrate that states with predominantly rural communities have fewer citizens receiving dialysis than other states. *See* Relman & Rennie, *supra* note 55, at 997.

103. The AMA supports the establishment of a "bright line" rule governing physician investment and referral practices to facilitate compliance. *AMA Statement, supra* note 13, at 7.

their practice to areas within one state,[104] thus discrepancies in state regulations will not affect most practitioners. Conflicting state regulations may affect corporate health care providers who deliver care in more than one state. Corporate providers, however, possess the administrative capabilities to stay abreast of disparate state regulatory structures.[105] Moreover, the central benefit of decentralization—the ability of states to enact regulations responsive to local needs—outweighs the complexity created by individual state regulation.

2. *States Currently Regulate Similar Physician Conduct*

The states are able to regulate physician investment and referral behavior because state laws currently oversee related conduct. In addition, decentralization will not require the creation of new enforcement structures. Many states have already established the means to regulate physician conduct.

a. *State Regulations Affecting Physicians*

The states can claim special knowledge in the regulation of physician conduct,[106] and their expertise could be used to regulate physician investments in referral facilities. States already regulate business investment in general and physician conduct specifically.[107] In the process of enacting and enforcing existing state regulations, the states have acquired unique and detailed knowledge about the activities of physicians in their communities. A logical extension of the states' regulatory power over physicians is to permit the states to establish and enforce limitations on physician referral practices involving physician investment.

b. *The Precedent for State Regulation When Federal Monies Are Involved*

Devolving responsibility for regulating physician investment to the states, even where federal money is involved, proves sensible when the proscribed conduct differs between states. Congress recognized the advantages of decentralized enforcement when it provided financial incentives for the states to establish Medicaid Fraud Control Units

104. Interview with Dr. Fred Connell, Associate Professor, Department of Health Services, University of Washington School of Medicine, in Seattle, Washington (Mar. 2, 1990).

105. *See generally* R. SHOULDICE & K. SHOULDICE, *supra* note 61, at 66–100 (outlining the organizational structure of health maintenance organizations).

106. *See supra* notes 51–54 and accompanying text (reporting on state regulation of physician investment and referral behavior).

107. *Id.*

(MFCUs).[108] Currently, MFCUs investigate and prosecute fraudulent conduct in thirty-eight states.[109]

In other federally-funded programs where the distribution needs vary among the states, Congress has permitted states to assume regulatory responsibilities. The education system provides an analogy. The federal government relies on the states to enact regulations for the efficient distribution of federal educational grants.[110] The federal government recognized the need to allow states to control the allocation of federal education grants because educational priorities vary among the states.[111] Demographic variations, cultural and linguistic differences, and income disparities result in divergent educational needs in each state. These differences prevent the federal government from effectively allocating federal educational monies within the state. The states' unique understanding of the educational needs of their citizens enables them to distribute federal educational resources more effectively than the federal authorities.

This logic extends to the health care industry. Health care needs, like educational needs, vary among the states.[112] State legislatures can establish regulations on physician investment and referral practices that respond to this variance more effectively than Congress. State legislatures have proven their competence in allocating federal funds in the educational arena. The states should be afforded the same opportunity in the health care arena.

Even where Congress does not funnel federal funds through the states, as with Medicare, the federal government has often relied on the enforcement powers of the states. For example, Congress relies on the states to enact regulations enforcing the objectives of the Clean Water Act.[113] The Act establishes minimum federal guidelines and

108. 42 U.S.C.A. §§ 1396a, 1396b(q) (West Supp. 1989). *See also* 42 C.F.R. pt. 455.21 (1988) (minimum procedural requirements for the operation of state MFCUs). The federal government subsidizes the first three years of operation of MFCUs. 42 U.S.C.A. § 1396b(q). In Fiscal Year 1988, the State MFCUs collected $4 million in fines through enforcement of the fraud and abuse statutes. OFFICE OF THE INSPECTOR GEN., DEP'T OF HEALTH AND HUMAN SERVS., SEMIANNUAL REPORT 41 (April–September 1988).

109. *See supra* note 47.

110. *See e.g.*, 20 U.S.C.A. § 2711(a)(3)(B) (West Supp. 1989) ("[T]he State educational agency may allocate the amount of grants . . . in such a manner as it determines will best carry out the purposes of this division.")

111. "[W]ithin these fiscal and targeting restraints, local and State agencies have full discretion . . . ." S. REP. NO. 222, 100th Cong., 2d Sess. 6–7, *reprinted in* 1988 U.S. CONG. & ADMIN. NEWS 107.

112. *See supra* notes 55–60 and accompanying text (examining differences in state health care needs).

113. 33 U.S.C.A. §§ 1251–1387 (West Supp. 1989).

permits the states to enact more stringent requirements.[114] The regulation of physician investment and referral behavior can be similarly managed. The federal government may establish minimum guidelines for regulating the investment and referral practices of physicians. Minimum federal guidelines would free the states to develop regulations reflecting their unique health care industry while assuring Congress that federal Medicare-Medicaid funds are not reimbursing fraudulent or abusive practices.

III. CONCLUSION

The federal Anti-Fraud and Abuse statute currently regulates the investment and referral practices of physicians. Two recent developments in the delivery and payment of medical services, however, mandate a new approach to regulating fraudulent investment and referral practices. The increasing popularity of physician corporations and the federal government's new prospective payment system have placed new pressures on health care providers to reduce costs. The Anti-Fraud and Abuse statute unnecessarily limits the physician's ability to respond to these pressures.

Decentralizing the regulation of physician investment and referral behavior will provide a means of regulating fraudulent behavior amid changes in the delivery and payment of health care. If Congress decides to decentralize the regulation of physician investment and referral behavior, state legislatures should design regulations to balance the importance of regulating physician fraud and abuse with the importance of fostering competition in the health care industry. Balancing regulation and competition can produce statutes that deter fraudulent investment and referral practices while encouraging competitive health care practices.

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114. *Id.* § 1342(b).